

Application No.: 10/087,198

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REMARKS**Amendments to the Claims**

In response to the Office Action, dated August 31, 2004, the subject application has been amended to more specifically recite the invention and distinguish over the prior art. All of the claims have now been limited to supplementing the sow feed with L-carnitine or a salt thereof and chromium tripicolinate. This latter compound, as clearly set forth in the specification and examples, is the preferred chromium salt for use in the instant invention. To further support the factual assertions made herein, enclosed is a Declaration by Robert D. Goodband Under 37 C.F.R. § 1.132 (hereinafter "the Goodband Declaration"). Dr. Goodband is one of the inventors of the subject application and a well respected expert in the field of swine nutrition.

Introduction

The data set forth in the specification shows the synergistic effect of these two compounds when used to supplement sow feed over at least two gestation periods, particularly with respect to the unexpected improvement in the farrowing rate. Note particularly, page 15 of the Specification, Table V, line 30, where the data show a 10% increase in farrowing rate (FR%) in the second parity by supplementing the sow feed in accordance with the method of the invention. In contrast, the L-carnitine and the chromium picolinate, when used alone, showed no improvement.¹ Please note the Examiner's recognition of synergism in the sentence bridging pages 4 and 5 of the Office Action dated June 20, 2003. The sentence reads as follows:

"In the second parity, there may be evidence of synergism in the data wherein the sows were bred by day 18, farrowed, first service farrow rate % and percentage of weaned parity [1] sows that farrowed in parity 2 (page 15 of the instant specification)."

¹ The Goodband Declaration, ¶ 4.

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Applicants acknowledge with appreciation the withdrawal of the rejections in the Office Action dated June 20, 2003 of the claims under 35 U.S.C. § 102(b).

It is noted that the claims now stand rejected solely on 35 U.S.C. 103(a) over:

Musser et al., Effects of L-Carnitine on Performance of Gestating and Lactating Sows, Swine Day, 1997 (IDS of 6/20/03, Document #2);

Trottier et al.; Effect of Supplemental Chromium Tripicolinate on Sow Productivity and Blood Metabolites, 1998 (IDS of 12/18/2002, Document #9);

J. Arthington, Millennium Technologies, The Original L-Carnitine/Chromium Picolinate Supplement. How and Why it Works? 4/27/00, (IDS of 5/8/02, Document #10); and

Samland et al., Effect of L-Carnitine and Chromium Nicotinate on the Ovulation and Fertilization Rates of Gilts, 1999 (IDS of 5/26/04, Document #CB).

Musser et al.

It will be recalled that broadly stated, the subject invention relates to the improvement of the "reproductive performance" of sows. This term is used to describe numerous and often unrelated aspects of performance of sows and/or of piglets born. As noted by the Examiner, Musser et al. teach adding L-carnitine in an amount of 50 ppm to a sow diet to assess gestation and lactation and litter performance, particularly increases in the litter birth and weaning weights and the number of piglets born alive. Applicants' Specification at Page 15 (Table V), lines 13, 25, and 35 reports these effects. On the other hand, and most importantly, Musser et al. unequivocally state on page 33, top of right column, that an improved farrowing rate is *not* demonstrated with L-carnitine alone.² The reference states that:

² The Goodband Declaration, ¶ 7.

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“No differences were observed in the subsequent days to estrus or *farrowing rate*....”
(emphasis added).

Accordingly, one skilled in the art would be discouraged from using this particular nutrient to improve farrowing rate.³

Further, as an additional distinction over Musser et al., the Examiner acknowledges that this reference does not teach the use of L-carnitine with any trivalent chromium salts. Office Action, dated August 31, 2004, page 4, line 4.

Trottier et al.

As to Trottier et al., the Examiner notes that the chromium tripicolinate added to the sow diet “increase[s] sow productivity through [an] increasing litter size” and “reduce[s] wean to estrus interval.” Office Action, dated August 31, 2004, page 4, lines 5-8. These two factors also relate to reproductive performance in general, but there is no specific teaching that the farrowing rate in the second parity improves with the addition of the chromium compound.⁴ That the sows in Trottier et al. were studied for three consecutive farrowings and that there was an increased litter size in cycle two are independent measurements of reproductive performance, and have nothing to do with increasing the farrowing rate. In Trottier et al., “[f]or all parameters analyzed, [the] individual sow was considered the experimental unit”, not a population of sows as would be required for proper analysis of the farrowing rate. Trottier et al., page B-2, at paragraph 4. Trottier et al. does not even discuss farrowing rates.

Moreover, the Examiner recognizes that Trottier et al. does not teach the addition of L-carnitine with a chromium salt. Office Action, dated August 31, 2004, page 4, line 4.

³ Id.

⁴ The Goodband Declaration, ¶ 8.

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Samland et al.

Samland et al. teach the addition of L-carnitine and chromium nicotinate as part of a gilt diet. It makes no reference, however, to a combination with chromium *picolinate*, the salt of chromium to which the claims are now limited.⁵ The Examiner recognizes that the feeding regimen claimed by the Applicants is not shown by this reference, stating specifically that the combination fed to the gilts in Samland et al. was “not through at least two gestation periods.” Office Action, dated August 31, 2004, p. 4, line 19. Indeed, the test subjects of the experiment were gilts, and the sows were not bred as part of the experiment. Samland et al., p. 33, paragraph headed “Experimental Design.” While this, of course, establishes the novelty of the subject invention, the Examiner neglects to mention that the reference states at page 33 under the heading “Results”:

“Statistical analysis, using initial blood values as covariates, showed no effect of L-carnitine or chromium treatments on insulin, glucose, or IGF-1” and that “[n]o L-carnitine x CrNic interactions were observed.”

Thus, Samland et al. teaches away from the combined use of both L-carnitine and a chromium compound (chromium nicotinate) as no synergistic effect arising from the combination was found.⁶ Further, Samland et al. never employed the combination now claimed, i.e., supplementation of sow feed with both L-carnitine and chromium *tripicolinate*. Nonetheless, the Examiner takes the position that “it would have been obvious to supplement fed with chromium and L-carnitine motivated by the teachings of Musser et al. and Trottier et al....” Office Action, dated August 31, 2004, p. 4, lines, 19-20.

It is difficult to understand upon what basis the Examiner finds such motivation. She notes that Musser et al. and Trottier et al. show the use of L-carnitine and chromium tripicolinate, respectively, used alone, and that Samland et al. show the combination chosen by Applicants. But

⁵ The Goodband Declaration, ¶ 6.

⁶ *Id.*

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the Examiner says nothing about the failure of these reference to show Applicants' unexpected benefit that the claimed combination that improves farrowing rate!

Case Citations

The cases cited by the Examiner on page 5 of the Office Action, dated August 31, 2004, are readily distinguishable. In four of the cases, the appellants' claims are held to be obvious because there was a lack of factual evidence in the record supporting their argument that their claimed combination of elements provided unexpected results over the prior art. The clear implication is that the decision would have been different where the appellant proffers more evidence. *In re Kerkhoven*, 626 F.2d 846 (CCPA 1980)⁷; *In re Paul Lindner*, 457 F.2d 506 (CCPA 1972)⁸; *In re Dial*, 326 F.2d 430 (CCPA 1964)⁹; *In re Shannon*, 356 F.2d 548 (CCPA 1966).¹⁰ In the instant case, experimental evidence showing "unexpected properties" is, as noted above, already of record.

In re Crockett, 279 F.2d 274 (CCPA 1960), was also cited by the Examiner. This case too is not pertinent. It concerns the addition of two compounds to cast iron, both of which were

⁷ In *Kerkhoven*, the court did not consider evidence of unexpected advantages because comparative test data offered by appellant as "evidence of his claimed method... [was] not commensurate in scope with the claims." 626 F.2d at 850.

⁸ In *Lindner*, the court declared that a person having ordinary skill in the art would expect that a mixture of the dispersants (cited in prior art references), would also be a dispersant. In *Lindner*, the Appellant conceded a case of prima facie obviousness, but asserted that "a synergistic effect is produced and properties are obtained and results are achieved which are unobtained and unobtainable with either the (a) or (b) dispersants alone." 457 F.2d at 508. The court rejected this argument stating that allegations that synergistic results are obtained with claimed compositions was not supported by factual evidence.

⁹ The decision in *In re Dial*, was based on fact that "[t]here is no evidence in the record establishing that appellants' combination of stabilizing agents is any more effective....", and that appellants' argument cannot be supported by "suppositions... rather than actual observations...." F.2d 430 at 432-33.

¹⁰ In *In re Shannon*, the court found a patent invalid as obvious stating that, "[t]he question of obviousness, however, is so closely tied to the facts of each particular case that prior decisions in cases involving different facts are ordinarily of little value in reaching a decision." 356 F.2d at 551. Importantly, the court noted that "comparative evidence is clearly needed" where the appellant argues the comparative benefit of their invention. *Id.*

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individually known to promote nodular structure formation. The Court found that although the combination produced a cumulative "effect somewhat greater than the sum of their [known] separate effects" that the claim was not patentable. The instant invention is readily distinguishable, since neither the individual component nor the most closely related combination thereof improved farrowing rates. Applicants' own data in Table V of the Specification and the prior art establish the deficiency of the individual components to enhance farrowing rates. Further, Samland et al. reported that the related combination was of little utility. The effect discovered by Applicants was not, as in the case of *In re Crockett*, cumulative, but rather wholly unique and surprising.

J. Arthington

The final reference relied on by the Examiner, J. Arthington, shows the use of L-carnitine and chromium picolinate to supplement swine feed to reduce fat deposition during the protein phase of growth, not to increase farrowing rates. The Examiner admits that reduced fat deposition during the protein phase of growth is unrelated to enhancement of "reproductive performance." Office Action, dated August 31, 2004, page 6, line 4. Further, the phases of swine J. Arthington is concerned with are not and cannot be involved in reproduction.¹¹

The citation of J. Arthington in combination with Samland et al. concerning insulin secretion etc. is particularly misplaced, since Samland et al. teaches away from Applicants' invention. Samland et al. teaches only that using chromium nicotinate with L-carnitine yields essentially no discernable beneficial enhancement of Insulin and Insulin-like Growth Factor production when fed to gilts. Further, Samland et al. does not teach anything about the combination improving second parity farrowing rate.

Conclusion

To conclude, the most surprising fact (certainly in light of the prolonged prosecution of the instant application), is that the Office Action, dated August 31, 2004, never even mentions that

¹¹ The Goodband Declaration, ¶ 9.

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Applicants have discovered a viable method of increasing farrowing rate after two periods of gestation. This is an invention of monumental importance that has achieved substantial commercial success. Evidence supporting Applicants' "unexpected results" is provided in the Specification and in the enclosed Goodband Declaration; hence, the cases cited by the Examiner where "unexpected results" were not adequately supported by factual evidence are rendered obsolete. Applicants' "unexpected result" is the *sine aqua non* for establishing patentability, yet it has now been totally ignored by the Examiner.

That the Examiner's position is certainly *not* the law, is shown by the citation of the CAFC cases on page 11 in Applicants' response to the non-final Office Action of May 26, 2004. Here, Applicants restate that it is black letter law that patentability is not barred by prior art which merely makes an invention "obvious to try," where the inventors subsequently establish surprising and unexpected results. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); see *In re Eli Lilly & Co.*, 902 F.2d 943 (Fed. Cir. 1990). Further, "unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely 'icing on the cake.'" *Hybritech Inc.*, 802 F.2d at 1380 (emphasis in the original). The Examiner has made no attempt to refute these cases.

As noted above, to facilitate the allowance of the subject application, Applicants have now limited the trivalent chromium compounds in the claims to *chromium tripicolinate*. This preferred chromium salt is the specific compound utilized in the examples set forth in the subject application.¹² In addition to limiting the claims to the preferred species, this amendment equivocally distinguishes over the Samland et al. references where the combination of nutrients is limited to that of L-carnitine with chromium *nicotinate*. It is believed that this limitation further distinguishes the prior art and enhances Applicants' arguments for patentability.

¹² The Goodband Declaration, ¶ 3.

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